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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,736	11/14/2001	Richard Philpott	56066/45858	9454

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EXAMINER	
GOLDBERG, JEANINE ANNE	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,736	PHILPOTT ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,7-27,29-32 and 35-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,7-27,29-32 and 35-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed January 20, 2004. Currently, claims 2-4, 7-27, 29-32, 35-43 are pending.

2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.

3. Any objections and rejections not reiterated below are hereby withdrawn in view of the amendments to the claims or applicant's arguments.

4. This action contains new grounds of rejection necessitated by amendment.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A1) Claims 29-32 are indefinite because the method of Claim 30 is directed to a method of isolating and analyzing genetic material. The final process step in the method is directed to detecting contamination of the sample. The method also recites analyzing the sample immediately prior to this step. Thus, it is unclear whether the method is a method for detecting contamination or a method of isolating/analyzing genetic material. Since the claim contains a separate step for analyzing the sample, it

appears as though the final process step may not be required to complete the claimed method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 2-4, 7-27, 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Staub et al. (US Pat. 6,187,540, February 2001) as evidenced by Gibco BRL Products Catalog (FTA Card, page 2-7, 1999) and Burgoyne (US Pat. 5,496,562, March 1996).

Staub et al. (herein referred to as Staub) teaches a method of newborn identification and tracking. Staub teaches a method of collecting newborn and maternal samples prior to discharge from the hospital to be collected on a single card. The card is then either stored or analyzed. Specifically, Staub teaches that a preferred sample type is a buccal swab which is painless to collect (col. 7, lines 5-10). Staub teaches obtaining a patient with saliva which produces a suspension comprising cells comprising genetic material. The saliva is applied to the buccal swab (col. 7, lines 15-16). The cells collected on the buccal cotton or sponge swabs are contacted or blotted onto FTA paper (a second solid medium). FTA paper is matrix which contains preserving means

including a weak base, a chelating agent and an anionic surfactant. The sample is then forwarded to a genotyping location to obtain analysis of the genetic material (see issued Claim 1, for example)(limitations of Claim 7, 2, 4, 10). Staub teaches that it is important that the sample cards are rendered tamper-proof to ensure that samples have not been compromised (col. 4, lines 65-68). Staub teaches that the tamper-proof collection device is examined to ensure that tampering, a form of contamination, has not occurred (see Claim 1d, for example)(limitations of Claim 25). Additionally, Staub's system is directed to detect whether newborn/mother pairings are correct or whether there is an improper pairing such that contamination from an inappropriate sample occurred, i.e. the baby does not belong to the mother (limitations of Claim 30-32).

With respect to Claim 8, the baby or the mother, a biological sample, is obtained (limitations of Claim 9). The buccal swab isolates cells from the sample on a first solid medium. The swab is then blotted on the FTA paper.

With respect to Claim 11-15, 21-24, 26-27, a saliva sample is obtained and cells are isolated on a first solid medium. The buccal swab is then blotted on FTA paper which lyses cells for analysis of the genetic material.

With respect to Claims 16-18, the baby or the method is obtained and cells are isolated on a solid medium, the buccal swab and blotted on FTA paper. It is noted that genetic material from a virus may be present on a buccal sample.

With respect to Claims 19-20, saliva, a non-solid biological sample from a human is obtained by isolating cells from the human onto a buccal swab. The swab is then contacted with FTA paper and analyzed.

The instant specification teaches FTA coating spontaneously lyses leukocytes releasing the genomic DNA (page 15 ,lines 5-6). The instant specification cites the chemical coating solution as described in 5,496,562. Burgoyne (US Pat. 5,496,562) teaches preparing a paper sorbed with preserving agents including SDS, EDTA and Tris (col. 4, lines 35-40). Burgoyne specifically teaches the composition sorbed on the solid support is a weak base, a chelating agent and an anionic detergent (col. 3, lines 15-30)(limitations of Claim 3). FTA paper is a trademark which cites to the 5,496,562 patent. As provided by Gibco BRL Products catalog, FTA paper is impregnated with a proprietary formulation. Moreover, Gibco teaches that the product is subject to Patent 5,496,562.

Therefore the FTA paper taught by Staub inherently has a weak base, a chelating agent and an anionic detergent sorbed thereto, as evidenced by the instant specification and Burgoyne.

7. Claims 4, 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Kathariou et al. (US Pat. 6,503,747, January 2003) as evidenced by www-biology.ucsd.edu/labs/aroian/protocols/electroblot.htm.

Kathariou et al. (herein referred to as Kathariou) teaches a method for analyzing genetic material. Mutants from 96-well plates were inoculated with a 48 prong replicating device on agar plates (first solid medium) and grown overnight. Bacterial colonies were transferred onto nitrocellulose membranes (second solid mediums) presoaked in Twobin transfer buffer. The nitrocellulose membranes were dried and

processed using immunoblot procedures (col. 18, lines 30-40)(limitations of Claim 7). The colonies were dissociated from the culture plates (limitations of Claim 4).

The art teaches Towbin transfer buffer is a solution of Tris, Glycine, SDS, MeOH at a pH of about 8.3. Towbin is considered a preserving means. It is noted that the instant specification fails to provide any particular definition for preserving means as required by 112/6th.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staub et al. (US Pat. 6,187,540, February 2001) as evidenced by Gibco BRL Products Catalog (FTA Card, page 2-7, 1999) and Burgoyne (US Pat. 5,496,562, March 1996) in view of Robertson (US Pat. 6,153,104, November 2000).

Staub et al. (herein referred to as Staub) teaches a method of newborn identification and tracking. Staub teaches a method of collecting newborn and maternal samples prior to discharge from the hospital to be collected on a single card. The card is then either stored or analyzed. Specifically, Staub teaches that a preferred sample type is a buccal swab which is painless to collect (col. 7, lines 5-10). Staub teaches obtaining a patient with saliva which produces a suspension comprising cells comprising genetic material. The saliva is applied to the buccal swab (col. 7, lines 15-16). The cells collected on the buccal cotton or sponge swabs are contacted or blotted onto FTA paper (a second solid medium). FTA paper is matrix which contains preserving means including a weak base, a chelating agent and an anionic surfactant. The sample is then forwarded to a genotyping location to obtain analysis of the genetic material (see issued Claim 1, for example)(limitations of Claim 7, 2, 4, 10). Staub teaches that it is important that the sample cards are rendered tamper-proof to ensure that samples have not been compromised (col. 4, lines 65-68). Staub teaches that the tamper-proof collection device is examined to ensure that tampering, a form of contamination, has not occurred (see Claim 1d, for example)(limitations of Claim 25). Additionally, Staub's system is directed to detect whether newborn/mother pairings are correct or whether there is an

improper pairing such that contamination from an inappropriate sample occurred, i.e. the baby does not belong to the mother (limitations of Claim 30-32).

The instant specification teaches FTA coating spontaneously lyses leukocytes releasing the genomic DNA (page 15 ,lines 5-6). The instant specification cites the chemical coating solution as described in 5,496,562. Burgoyne (US Pat. 5,496,562) teaches preparing a paper sorbed with preserving agents including SDS, EDTA and Tris (col. 4, lines 35-40). Burgoyne specifically teaches the composition sorbed on the solid support is a weak base, a chelating agent and an anionic detergent (col. 3, lines 15-30)(limitations of Claim 3). FTA paper is a trademark which cites to the 5,496,562 patent. As provided by Gibco BRL Products catalog, FTA paper is impregnated with a proprietary formulation. Moreover, Gibco teaches that the product is subject to Patent 5,496,562.

Staub does not specifically teach obtaining the first matrix using a vacuum.

However, Robertson teaches a method of body fluid separation. The methods uses a device comprising a chamber, a cooperating filter, a second chamber, where the first and second chamber has a connection to vacuum with filters on each side and a removable closure in the form of end caps. As seen in Figure 1 the device is provided. Robertson teaches that the invention provides equipment of notable simplicity and relatively low cost with method steps well within the capabilities of junior members of laboratory staff, to enable separation of a body fluid into various of its component (col. 1, lines 30-35). Robertson teaches obtaining a biological sample, such as saliva (col. 3, lines 25-26). The biological sample is in a suspension comprising genetic material, as

saliva comprises cells. An apparatus comprising a chamber, two solid mediums, a vacuum means is seen in Figure 1. The sample is applied to one side of a filter, vacuum is applied to the opposite side of the filter to draw the liquid, leaving the cells on the first solid support. Robertson teaches that to gather the cell contents of the leukocyte cells, it is most desirable that a filter membrane is provided to isolate the DNA content of the cells form other cell debris washed from the filter (col. 4, lines 60-65).

Therefore, it would have been prima facie obvious to one of ordinary skill at the time the invention was made to have modified the method of Staub to include the vacuum steps of Robertson to prepare the first solid support. The ordinary artisan would have been motivated to have taken a saliva sample and place the sample in a vacuum to obtain a solid support comprising cells. Given the teachings of Staub, the ordinary artisan would have taken the solid support comprising the cells and blotted them onto FTA paper for the express benefit of preserving the genetic material in an inexpensive and space conserving manner (col. 7, lines 30-35 of Staub). Robertson teaches that using a vacuum allows for low cost procedures using relatively simple equipment with attendant procedures well within the capabilities of junior members of laboratory staff, to enable separation of a body fluid into various components (col. 1, liens 30-35 of Robertson). The ordinary artisan would have recognized the simplicity of separation of cells using the vacuum and would have been motivated to have separated cells using the method described by Roberston. Once the cells were immobilized on a solid support using the method of Robertson, the ordinary artisan would have been motivated to have transferred the cells to FTA paper. Staub teaches that cells may be

transferred from solid supports by blotting onto FTA paper. FTA paper is a convenient method for storing blood samples for DNA testing. Therefore, the ordinary artisan would have been motivated to have collected any number of samples using the vacuum method of Staub to immobilize cells prior to blotting them onto FTA paper for the benefit of storage and preservation of the sample for later analysis.

Conclusion

10. **No claims allowable over the art.**

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 6:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (571)272-0507

J. Goldberg

Jeanine Goldberg
Patent Examiner
February 10, 2004

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2/10/2004